

REMARKS

Claims 11-35 are pending. Claims 11, 24, 25, 34, and 35 have been amended, and claims 26-33 have been canceled without prejudice. Therefore, claims 11-25, 34, and 35 are pending in the application.

Applicants have amended claims 11 and 35 in the manner suggested by the Examiner to clarify both the amount and viability of the binucleate *Rhizoctonia* strain. Specifically, Applicants have inserted the term “viable” immediately before the first occurrence of “binucleate” and have added the phrase “in an amount effective to protect a plant from pathogenic fungi” immediately after the first occurrence of “strain.” Applicants have also amended claims 11, 34, and 35 so as to include the phrase “and which confers protection against pathogenic fungi to the plant” immediately after the first occurrence of “SEQ ID NO: 20.” Applicants have replaced the phrase “wherein providing includes” with “further comprising” in each of claims 24 and 25. Applicants have also deleted the term “associated” in claim 34 and replaced it with “inoculated.” Support for these amendments can be found throughout the specification, e.g., at page 4, line 1 through page 6, line 14; and page 17, lines 1-26. No new matter is introduced by these amendments.

The amendment to the specification filed with Applicants' response is objected to under 35 U.S.C. 132 because it allegedly introduces new matter into the disclosure. According to the Office Action:

Applicants' assertions that the skilled person would recognize that the sequences according to SEQ ID NOS. 1 to 14 were target sequences from the isolates themselves and not primers directed thereto and that they are within SEQ ID NOS. 15 to 25 is noted. However no alignment or other evidence is provided to substantiate these contentions (Office Action, page 3, lines 7-10, emphasis added).

Applicants submit herewith as Exhibit A a sequence alignment that indicates SEQ ID NOS.: 1 to 14 are contained within the larger sequences, i.e., SEQ ID NOS.: 15 to 25. E.g., see SEQ ID

NO: 20, which is aligned with each of SEQ ID NOS: 7, 9, 11, 2,12, and 13. E.g., the sequence of SEQ ID NO: 7 is found at nucleotides 62-80 at SEQ ID NO: 20; the sequence of SEQ ID NO: 9 is found at nucleotides 93-103 at SEQ ID NO: 20; the sequence of SEQ ID NO: 11 is found at nucleotides 150-169 at SEQ ID NO: 20; the sequence of SEQ ID NO: 2 is found at nucleotides 160-174 at SEQ ID NO: 20; the sequence of SEQ ID NO: 12 is found at nucleotides 173-188 at SEQ ID NO: 20; and the sequence of SEQ ID NO: 13 is found at nucleotides 189-214 at SEQ ID NO: 20. Applicants submit that this alignment relationship would be evident to the skilled person, and that the amendment to correct the identification of the sequences as target sequences does not introduce new matter into the specification. Applicants respectfully request reconsideration in view of the foregoing remarks and Exhibit A.

Rejections under 35 U.S.C. 112, second paragraph

Claims 11-25 and 34-35 are rejected for allegedly being indefinite. The individual rejections are addressed separately by Applicants below.

According to the Office Action: "Claim 11 is vague and indefinite in that neither the amount of the strain nor the viability of the strain is claim designated. Language such as 'viable' and 'in an amount effective to protect a plant from pathogenic fungi' would be remedial" (Office Action, page 3, lines 22-24). This rejection is rendered moot in view of the amendment to claim 11. Since claims 12-25 depend from claim 11, Applicants respectfully request that the rejection of these dependent claims be withdrawn on the same grounds.

The Office Action alleges that claims 19 and 20 are "confusing in that the distinction between inoculating and allowing to be colonized is unclear. Alternatively, it is unclear how colonization with a particular strain is 'allowed' in the absence of inoculation" (Office Action, page 3, lines 25-28).

Applicants respectfully disagree. First, the step of inoculation is considered to comprise the introduction of the strain to the plant, while the step of allowing colonization involves additional subsequent growth of the strain after its introduction to the plant. The specification, e.g., at page 17, lines 1-20, sets forth this distinction between inoculation and subsequent

colonization. Applicants submit that the distinction between inoculating and allowing to be colonized is clear and definite to one of skill in the art reading the instant specification. Turning to the second point raised in the rejection, Applicants note that claim 20 depends from claim 19. As such, claim 20 includes all of the limitations of claim 19. Further, claim 20 recites “further comprising allowing the seeds to be colonized...” (emphasis added). Given these facts, claim 20 clearly precludes practicing the step of colonization in the absence of inoculation. Applicants respectfully request that the rejection of claims 19 and 20 be withdrawn.

According to the Office Action: “Claim 34 is vague indefinite and confusing in the provision of a plant, seed, or seedling ‘associated with’ certain binucleate *Rhizoctonia*” (Office Action, page 3, lines 29-30). Applicants submit that the rejection no longer applies to claim 34 as amended.

Claim 35 is rejected as being unclear as to the protective nature of the fragment of the mycelium. Applicants have amended claim 35 in the same manner as claim 11, i.e., to recite that the strain is viable and is provided in an amount effective to protect the seed, plant or seedling from pathogenic fungi. Applicants submit that the rejection no longer applies to claim 35 as amended.

Claims 24 and 25 are rejected as being vague and indefinite in the recitation of “wherein providing includes selling”. Applicants have amended these claims to recite that the method further comprises selling a plant. Applicants submit that the rejection no longer applies to claims 24 and 25 as amended.

Rejection under 35 U.S.C. 112, first paragraph

Claims 11-25 and 34-35 are rejected "as failing to comply with the written description requirement" (Office Action, page 4, lines 8-9). Specifically, the Office Action states:

The claims are broadly drawn to protection of plants with strains characterized as having an ITS1 DNA which has 90% homology to SEQ ID NO: 20. In contrast, the specification only provides guidance regarding the use of strains having a specific sequence, in this instance, SEQ ID NO: 20 (Specification page 5, paragraph 4). No guidance is presented for the alteration of any part of any recited sequences or of SEQ ID NO: 20, specifically. No guidance is presented regarding the evaluation of strains selected at random for the required homology to SEQ ID NO: 20 or regarding which part of that sequence is required to result in effective protection of plants with the strain. Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the claimed invention (Office Action, page 4, lines 13-21).

Applicants respectfully disagree. According to the Manual of Patent Examining Procedure (MPEP):

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Vas-Cath, Inc. v. Mahurker*, 935 F.2d at 1563, 19 USPQ2d at 1116. ... It is now well accepted that a satisfactory description may be in the claims or any other portion of the originally filed specification (MPEP, 8th edition § 2163).

The instant claims cover methods for protecting plants from pathogenic fungi by providing binucleate *Rhizoctonia* strains, which are characterized as having an ITS1 sequence which is at least 90% homologous with SEQ ID NO: 20, and allowing these strains to grow with the plants. The instant claims are fully supported by the specification, e.g., at page 4, lines 3-5 and 17-19 and page 5, lines 15-91; and, e.g., claims 1, 4 and 5 as originally filed:

Claim 1: A method for the protection of plants from pathogenic fungi which comprises biocontrol by the use of a binucleate *Rhizoctonia* strain selected by molecular detection of the ITS ribosomal sequence.

Claim 4: The method according to claim 1 wherein the binucleate *Rhizoctonia* strain is selected using the ITS1 data.

Claim 5: A method according to claim 1 wherein the strain has an ITS1 sequence which is at least 90% homologous with one of SEQ ID NO: 15, SEQ ID NO: 16, SEQ ID NO: 17, SEQ ID NO: 18, SEQ ID NO: 19, SEQ ID NO: 20, SEQ ID NO: 21, SEQ ID NO: 22, SEQ ID NO: 23, SEQ ID NO: 24, SEQ ID NO: 25, SEQ ID NO: 26, SEQ ID NO: 27, or SEQ ID NO: 28 (emphasis added).

Applicants' original disclosure clearly and fully supports all the elements recited in claims 11-25 and 34-35. In addition, as described below, the genus recited in the claims also complies with this requirement.

Applicants have provided a representative number of species and thereby have provided written description of the genus of sequences having at least 90% homology to SEQ ID NO: 20. Figure 1 of the instant specification recites a number of species that are about 90% homologous or greater, namely, strains AGA, CAG2, AGD, AG-I, AG-G, AG-J, RH2815, Eab-S3, Eab-F5, Eab-F6, Eab-S6, Eab-S1, Eab-F2, and Eab-F1. The homology relationship between these species can be seen from the paper published by the inventors (Gonzales et al.), which was submitted with Applicants' previous reply. As can be seen from the inventors' paper, strain Eab-F1, which includes SEQ ID NO: 20, falls into group 5 of the various clusters identified in Figure 2 of that paper (see page 608 of Gonzalez) as do strains Eab-F5, Eab-F6, Eab-S6, Eab-S1, and Eab-F2. According to Table 2 of Gonzalez et al, which shows the percentage of sequence divergence among the various groups, the divergence within group 5 is 0.00-1.06%. The specification also describes strains AGA, CAG 2 and AGD, which are in group 1. According to Table 2, group 1 differs from group 5 by 10.84-12.80%. The specification also describes strains RH2815 and Eab-S3, which are in group 7. According to Table 2, group 7 differs from group 5 by 6.27-8.35%. Finally, the specification also describes strains AG-I, AG-G, and AG-J, which are in group 6. According to Table 2, group 6 differs from group 5 by 4.56-6.30%.

Therefore, the instant specification provides teaching and guidance for a number of sequences having 90% or more homology with SEQ ID NO: ID 20. There is disclosure in the specification of at least eleven species within the 90% homology range, namely AG-I, AG-G, AG-J, RH2815, Eab-S3, Eab-F5, Eab-F6, Eab-S6, Eab-S1, Eab-F2, and Eab-F1. The claims require that the genus of nucleotide sequences does not have substantial variation since all of the variants must confer protection against pathogenic fungi to the plant and must have at least 90% identity to the reference sequence, SEQ ID NO: 20. This requirement imposes significant structural limitations on each member of the genus. The disclosed species are representative of the genus because all members have at least 90% structural identity with the reference compound and because of the presence of an assay which Applicants provided for identifying all of the at least 90% identical variants of SEQ ID NO: 20 that are capable of conferring protection against pathogenic fungi to the plant. One of skill in the art would conclude that Applicants were in possession of the necessary common attributes possessed by the members of the genus.

Furthermore, given that each of the sequences is provided in the present application, it would be a routine matter for the skilled person to assess the percentage sequence homology between the various sequences based on the information provided in the specification. Applicants also note that the claims as amended recite that the sequence is sufficient to provide protection from fungi to the plant. Again, determination of whether a particular sequence having 90% or more homology to SEQ ID NO: 20 would provide the claimed function would be a matter of routine determination for the person of skill in the art.

The Office Action also asserts that there is no clear indication that strains having the required homology and which are suitable for plant protection were freely available to the public. (Office Action, page 5, lines 3-11). The strains identified as F5, F6, S6, S1, and F1 were deposited under the Budapest Treaty. These deposits and their identification numbers are given at page 10 of the instant specification. All of these strains fall within group 5 as identified by Gonzalez et al, and therefore fall within the scope of the instant claims. Applicants hereby declare for the avoidance of doubt that this deposited material has been accepted for deposit

under the Budapest Treaty, and that all restrictions on the availability to the public of the materials so deposited will be irrevocably removed upon the granting of a patent.

Finally, the Office Action further suggests that the genus *Ceratobasidium* and *Rhizoctonia* are in different taxa. *Rhizoctonia* is in fact a so-called form genus, or anamorph genus. *Rhizoctonica* is a species complex which comprises a number of teleomorph genera, including the genus *Ceratobasidium*. Further details on the classification of *Rhizoctonia* can be found on pages 606 and 607 of the Gonzalez et al paper, as well as various reference text books, for example Peter Roberts "Rhizoctonia-forming fungi, a taxonomic guide" (1999) published by the Royal Botanical Gardens, Kew. SEQ ID NO: 20 therefore relates to the Eab-F1 isolate of the species *Ceratobasidium albasitensis*, which is a *Rhizoctonia* strain. Claim 11 relates to the use of certain *Rhizoctonia* strains having sequence similarity to the Eab-F1 isolate, several of which strains are disclosed in the application as filed. Applicants again submit that the instant claims are therefore fully enabled by the specification as filed.

Thus, the skilled artisan reading the disclosure as originally filed would reasonably conclude that Applicants were in possession of the claimed methods at the time of filing. Applicants submit that the instant claims satisfy the written description requirement set forth in 35 U.S.C. 112, first paragraph. Applicants submit that the instant claims meet the statutory requirements of 35 U.S.C. 112, first paragraph and respectfully request withdrawal of the rejection.

Rejection under 35 U.S.C. 102(b)

Claims 11-12, 18-23, and 34-35 are rejected as being anticipated by Herr, 1988 (Herr) or Cardoso *et al.*, 1987 (Cardoso). According to the Office Action:

Herr and Cardoso *et al.* each discloses processes of the protection of plants from fungi by using biocontrol with binucleate *Rhizoctonia*. (See, e.g., Table 5; Tables 2 and 3). Even though the reference is silent as to whether or not the strains used have the required sequence, the binucleate *Rhizoctonia* are effective in the protection of plants from fungi as claimed. Thus, it can reasonably be assumed that the strains inherently possess the required sequence (Office Action, page 6, lines 6-10, emphasis added).

Applicants respectfully disagree. Herr and Cardoso teach the use of several specific strains: AG4, CAG4, CAG5, and CAG7. The Cardoso paper refers specifically to strains AG4 and CAG5. Herr also refers to CAG 4, CAG 5 and CAG 7. None of these strains fall within the limits of the claims. They do not have 90% homology to SEQ ID NO: 20 and they are not binucleate.

Applicants refer to the phylogenetic tree (the expanded tree) that was submitted with the previously filed reply. This phylogenetic tree is an expansion of the tree delineated in Figure 2 of Gonzalez (page 608, the "Gonzalez tree"). It will be noted that the expanded tree is divided into two main branches, genus *Ceratobasidium*, and genus *Thanatephorus*. A comparison of this tree with the Gonzalez tree reveals that groups 1 to 7 inclusively of the Gonzalez tree are clustered within the genus *Ceratobasidium* of the expanded tree. Strains AG 4, CAG 4, CAG 5, and CAG 7, which are disclosed in Herr and Cardoso, however are located on the upper branches of the expanded tree, within the grouping referred to as the genus *Thanatephorus*. In addition, as outlined in Gonzalez, the genus *Thanatephorus* consists of multinucleate strains, rather than binucleate *Rhizoctonia*. The instant claims, however, require that the *Rhizoctonia* strains be binucleate strains. As such, the strains disclosed in Herr and Cardoso, which are multinucleate strains, fall outside the scope of the strains covered by the instant claims.

Applicants note that according to Table 2 of Gonzalez, the strains of group 4 differ from those of group 5, which contains SEQ ID NO: 20, i.e., Eab-F1, by at least 13.84%. The strains of group 4 are shown on the expanded tree in the cluster belonging to *Ceratobasidium cereale*. It will be apparent that the strains identified as CAG 4, 5, and 7 and AG 4 fall into the genus *Thanatephorus*. The CAG 4, 5, and 7 and AG 4 strains are in fact further removed from the group 5 strains (i.e., Eab-F1) than they are from the strains of group 4. This observation suggests that the CAG 4, 5, and 7 and AG 4 strains differ by more than 13% from the strain Eab-F1. Thus, in view of the foregoing, it cannot be reasonably presumed that Herr and Cardoso disclose binucleate *Rhizoctonia* strains having at least 90% homology to sequence ID 20. Indeed, the phylogenetic tree suggests that the Herr and Cardoso strains do not contain the sequences recited in Applicants' claimed methods.

Finally, Herr discloses experiments using biocontrol agents noted as, e.g., "BN-1," (binucleate *Rhizoctonia spp.* isolates, see, e.g., page 112 of Herr, Table 2). It does not appear that Herr deposited, characterized, or described these binucleate strains such that one of ordinary skill in the art would be able practice methods of plant protection using these strains. Therefore, Herr does not enable these strains. Thus, Herr cannot be applied as a reference under 35 U.S.C. 102(b) against the instant claims on the grounds that Herr does not contain an enabled disclosure.

Herr and Cardoso do not disclose, either explicitly or inherently, methods for protecting plants with binucleate *Rhizoctonia* strains having at least 90% homology to sequence ID 20. As such, Herr and Cardoso do not anticipate claims 11-25, 34, and 35. Applicants therefore respectfully request withdrawal of the rejection.

Rejection under 35 U.S.C. 103(a)

Claims 11-25, 34, and 35 are rejected as being unpatentable over Herr taken with Cardoso. The Office Action has acknowledged that both references are "silent" as to whether the Herr and Cardoso strains have the sequence required by the instant claims (i.e., at least 90% homology to sequence ID 20). The Office Action further asserts "it can reasonably be presumed

that the strains possess" the sequence required by the instant claims, i.e., the sequences recited in the instant claims are an inherent property of the Herr and Cardoso strains.

As discussed above, there is no teaching or suggestion, either explicit or inherent, in Herr or Cardoso to protect plants using binucleate *Rhizoctonia* strains having at least 90% homology to sequence ID 20. Applicants submit that the Office has not established a *prima facie* case of obviousness because there is no motivation or suggestion in Herr and Cardoso to modify the applied references to arrive at Applicants' invention. Applicants respectfully request that the rejection be withdrawn.

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Page : 16 of 16

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CONCLUSION

Applicants submit that all claims are in condition for allowance.

Enclosed is a \$420 check for the Two Month Petition for Extension of Time fee. Please apply any other charges or credits to deposit account 06-1050, referencing Attorney Docket No.: 15605-002001.

Respectfully submitted,

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SEQ ID NO: 15

AGAGGAAGTAAAAGTCGTAACAAGGTTTCCGTAGGTGAACCTGCGGAAGGATCATTATTGAATGA
TTGAATGA

ATATAGAGTTGGTTGTCGCTGGCTCCTCCGGGAGCATGTGCACGCTTTCTCTTTCATCCACACAC
ATATAGAGTTG (SEQ. ID.7) TCCTCCGGGAG (SEQ. ID.9)

CCGTAAAAAAGTCTT (SEQ ID 2)
ACCTGTGCACTTGTGAGACGGAGGACCGTAAAAAAGTCTTCCGTCTATTAAACCACACAAACCCC
AGACGGAGGACCGTAAAAAA (SEQ ID 11)

ACACAAACCCC
TTCCGTCTATTAAACC (SEQ ID12)

ATTGTATTTAAATTGAATGTAATTGATGTAACGCATCATTAGGAACT
ATTGTATTTAAATTG (SEQ ID 13)

SEQ ID NO: 20

TTAGAGGGGAATAAAAAGTCGTAACAAGGTTTCCGTAGGTGAACCTGCGGAAGGATCATTATTGA
TTGA
ATGAATATAGAGTTGGTTGTCGCTGGCTCCTCCGGGAGCATGTGCACGCTTTCTCTTTCATCCAC
ATGAATATAGAGTTG (SEQ ID. 7) TCCTCCGGGAG (SEQ ID. 9)
AGACGGAGGACCGTAAAAAA (SEQ ID. 11)
ACACACCTGTGCACTTGTGAGACGGAGGACCGTAAAAAAGTCTTCCGTCTATTAAACCACACAA
CCGTAAAAAAGTCTT (SEQ ID. 2)
TTCCGTCTATTAAACC (S. 12)
CCCCATTGTATTTAAATTGAATGTAATTGATGTAACGCATCATTAAACT
CCCCATTGTATTTAAATTG (SEQ ID. 13)

SEQ ID NO: 21

TTTAGAGGGAAGTAAAAGTCGTAACAAGGTTTCCGTAGGTGAACCTGCGGAAGGATCATTATTG
AATGAATATAGAGTTGGTTGTCGCTGGCTCCTCCGGGAGCATGTGCACACTTTCTCTTTCATCCA
TCCTCCGGGAG (SEQ ID. 9)

AGACGGAGGACCGTAAAAAA (SEQ ID. 11)

ACACAA
CACACACCTGTGCACTTGTGAGACGGAGGACCGTAAAAAAGTCTTCCGTCTATTAAACCACACAA
CCGTAAAAAAGTCTT (SEQ ID. 2)
TTCCGTCTATTAAACC (S.12)

CCACACAA

ACCCCATTTGTATTTAAATTG (SEQ ID. 13)
ACCCCATTTGTATTTAAATTGAATGTAATTGATGTAACGCATCATTAGAACT

ACCC-ATTGTATT (SEQ ID. 3)

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SEQ ID NO: 25

GTCGTAACAAGGTTTCCGTAGGTGAACCTGCGGAAGGATCATTATCGAATGAACAATGGGGATCG
(SEQ ID.8) TCGAATGAACAATGGGGATCG

GTTGTCGCTGGCTTCTTCATTGAGGCATGTGCACGCCTTTCTCTATTTTCATCCACACACACCTGT
TTCTTCATTGAGG (SEQ ID. 10)

GAACTTGTGAGACGGAGGACCGTAAAAAAGTCTTCTGTCTACATAAACTCCAATTTAATAAATCT
ACATAAACTCCAATTTAATAAATCT
GAATGTAATTGATGTAACACATCTTTAACT
G (SEQ ID. 14)

SEQ ID NO: 28

AGAGTTTGGTTGTAGCTGGTCCCTAATTAAGTGGGGGCATGTGCACACCTTTCTCTTTTCATCCC
CCCTA-TTAA---GGGG-CA (SEQ ID. 1)

ATACACACCTGTGCACCTGTGAGACAGATGTTTTCTAGAGGGGGAAGGAAC-TTTATTGGACCTAC
GGAACCTTTATTGGAC(S 5)
TCTCCTTGGACCTTCTGTCTAC